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March 26, 2003

Public Information and Records Integrity Branch (PIRIB)
Office of Pesticide Programs (OPP)
Environmental Protection Agency (7502C)
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460-0001

Attention: Docket ID Number OPP-2002-49

The United States Environmental Protection Agency (USEPA) issued a Federal Register Notice announcing the availability and opportunity for public comment on the "Preliminary Comparative Ecological Assessment for Nine Rodenticides." The notice was issued on January 29, 2003, with a 60-day public comment period ending March 31, 2003.

Thank you for the opportunity to respond to the USEPA's publication entitled "Potential Risks of Nine Rodenticides to Birds and Non-Target Mammals: A Comparative Approach," William Erickson and Douglas Urban, 2002. The California Department of Food and Agriculture (CDFA) is concerned about issues and concepts presented in the publication.

The CDFA would like to enter the enclosed document entitled "Comments of the California Department of Food and Agriculture on the USEPA's Preliminary Comparative Ecological Assessment for Nine Rodenticides," document entitled "Potential Risks of Nine Rodenticides to Birds and Non-Target Mammals: A Comparative Approach," into the public record.

If you have any questions please contact me at (916) 654-0768 or by e-mail at dschnabel@cdfa.ca.gov.

Sincerely,

Duane L. Schnabel, Senior Agricultural Biologist
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Plant Health and Pest Prevention Services

Enclosure

DS:cj

Comments of
The California Department of Food and Agriculture

On
The United States Environmental Protection Agency's
Preliminary Comparative Ecological Assessment for Nine Rodenticides,
Document Titled "Potential Risks of Nine Rodenticides to Birds and
Nontarget Mammals: A Comparative Approach"

In Response to:

Federal Register Vol. 68, Number 19, pages 4468-4470
Rodenticides; Availability of Preliminary Comparative Ecological Assessment

Submitted to:

Docket OPP-2002-049

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The California Department of Food and Agriculture's Comments on the United States Environmental Protection Agency's Preliminary Comparative Ecological Assessment for Nine Rodenticides

General Comments

1. The United States Environmental Protection Agency's (USEPA) Preliminary Comparative Ecological Assessment (PCEA) makes no mention of the benefits of the rodenticides evaluated and leads the reader to focus solely on their potential hazards and risks. The Federal Insecticide Fungicide and Rodenticide Act (FIFRA) § 2(bb) requires that the USEPA must take into account the economic, social, and environmental cost and benefits of the use of any pesticide when evaluating whether risks are unreasonable to man or the environment.

2. The generic methodology used in the PCEA does not take into account the different use patterns, use sites, application methods, exposure profiles, target pests, use restrictions, and formulation- or product-specific information that affects exposure and actual risks to nontarget species. In other words, the USEPA has not conducted an exposure analysis for any actual individual rodenticide products and thus should not characterize the document as "the Agency's preliminary assessment of potential risks to birds and nontarget mammals from nine rodenticides (PCEA Executive Summary, first sentence). The USEPA has only evaluated the inherent hazard of the active ingredients that are used in individual rodenticide products, not the risks from use of any products themselves. It is inappropriate to assume equal exposure for all registered rodenticide products, but this is the inherent assumption in the USEPA's methodology, whether stated or not. See further discussion below in the Comments on the USEPA's Methodology.

3. The USEPA has prepared a tabular comparative rating of potential risks (Table 47) based on a qualitative "weight-of-evidence" assessment, in which data are evaluated and risks (primary and secondary) are assigned a rating of high, moderate, or low. The USEPA does not explain how this "weight-of-evidence" assessment was performed, how the ratings were assigned, what the ratings mean (e.g., are these relative risks or absolute risks?; should we expect effects on individuals or populations of birds and/or mammals?), or how the ratings will be used by the Agency in a regulatory context. For example, what is the relationship between "high" risks as defined in the PCEA, if any, and those considered to be "unreasonable adverse effects on the environment" as defined in FIFRA § 3(c)(5)?

4. The PCEA does not discuss the scientific or regulatory rational for conducting the ecological assessment or explain how the results of the analysis might be used by the Agency. In addition, the USEPA does not address any follow-up activities or specific steps that the USEPA intends to take as a result of the ecological assessment, except to require avian reproduction studies for outdoor use rodenticides.

Comments on the USEPA's Methodology

Hazard versus Risk

1. There is a significant flaw in the approach and methodology used by the USEPA in its preliminary assessment. By consciously choosing to ignore any differences in exposure

between the rodenticides being compared (see comments below), the USEPA has effectively limited its analysis to one of hazard rather than risk. In its Guidelines for Ecological Risk Assessment (USEPA, 1998), the USEPA has defined ecological risk assessment as "a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors." The process includes three major phases: 1) problem formulation, 2) analysis, and 3) risk characterization. The analysis phase includes development of profiles of environmental exposure and effects of the stressor. According to the USEPA (1998), the exposure profile "identifies the receptor (i.e., the exposed ecological entity), describes the course a stressor takes from the source to the receptor (i.e., the exposure pathway), and describes the intensity and spatial and temporal extent of co-occurrence or contact. The profile also describes the impact of variability and uncertainty on exposure estimates and reaches a conclusion about the likelihood that exposure will occur." By the USEPA's own acknowledgment, it is clear that it has chosen not to develop exposure profiles for the rodenticides evaluated and, therefore, cannot define the outcome of its assessment as a risk assessment. While it is not always necessary or possible to characterize the likelihood of adverse effects in a quantitative manner, it is necessary to consider all of the various aspects of exposure (e.g., magnitude, duration, frequency) when drawing conclusions regarding risks. The USEPA clearly has not done this in the PCEA.

2. The distinction between a risk assessment and a hazard assessment is an important one, especially under the FIFRA registration standard (i.e., in order to be registered, the use of a pesticide shall not cause "unreasonable adverse effects on the environment"). The potential types of adverse effects that might occur (and the doses that might cause them) can be identified through the hazard assessment process; however, only by evaluating exposure and characterizing risk can it be determined if use of a pesticide will likely cause these adverse effects and whether these effects are unreasonable or not in terms of their effect on individuals and populations of nontarget organisms. While it may be appropriate for the USEPA to use results of a comparative hazard assessment to identify active ingredients for further evaluation in a formal risk assessment, it is inappropriate for the USEPA to use these results for registration decisions and/or to propose risk mitigation measures because actual risks have not been evaluated and quantified for specific rodenticide products and uses.

No Evaluation of Risks from Different Rodenticide Products and Use Patterns

1. The generic, "one size fits all" methodology used in the USEPA's PCEA does not take into account the different use patterns, use sites, application methods, exposure profiles, target pests, use restrictions, and formulation- or product-specific information that affects actual risks to nontarget species. Without specifically stating so, the ecological assessment evaluates the nine rodenticide active ingredients as if they were identical, interchangeable products, ignoring the fact that dozens of different products on the market with different formulations and use patterns (e.g., bait sizes, target species, use sites, application methods). For example, the USEPA makes no differentiation in their assessments between rodenticides used in the field for ground squirrel control versus those used "in and around homes" for control of commensal species. In its generic approach, the USEPA does not differentiate between rodenticide products with different application methods such as those used in bait stations versus those that are mechanically broadcast or placed by hand. This ignores the fact that potential nontarget species are often much different for these different application methods, as well as for products used in agricultural areas versus those used in urban areas. For example, 0.01 percent a.i. grain baits containing chlorophacinone and diphacinone are only registered for field use in California, yet in the PCEA they are

compared to all other rodenticide formulations and uses as if they were interchangeable. The USEPA's methodology may be acceptable for a preliminary hazard assessment where products are truly interchangeable in the marketplace, but it is totally inappropriate for a risk assessment where many of the factors that influence exposure and risk are ignored. In order to truly evaluate the risks of different rodenticides to birds and nontarget mammals, the USEPA must develop product-specific and use-specific exposure assessments that take into account differences between different products (e.g., pellet size, placement size, placement location, target species, etc.) as well as differences between different uses of the same product (e.g., spot baiting vs. broadcast baiting).

Lack of Exposure Assessment

1. Although conclusions are made regarding risks to birds and nontarget mammals, the PCEA does not include a quantitative exposure assessment for any of these organisms. In fact, it is stated in the PCEA Executive Summary that "in preliminary risk assessments, an assumption is made that birds and nontarget mammals are likely to be exposed to the pesticide without attempting to establish a quantitative measure of likelihood." Without a quantitative exposure assessment, risks should not be described as high, moderate, or low as in (Table 47), unless it is specifically stated that these are only relative or comparative risks, and not absolute or "real" risks. However, if we are worried about protecting birds and nontarget mammals, it is the absolute or real risks that we are concerned about, not the comparative risks. It is very possible for relative risks to be high while absolute or real risks are low. For example, because exposure was not accounted for in the assessment, it could easily be the case that a rodenticide given a "high" risk rating by the USEPA actually presents no real risk to birds and nontarget mammals due to actual exposure.

2. The USEPA acknowledges that secondary exposure estimates require consideration of residues in tissues of target organisms (PCEA Page 8); however, despite providing summaries of target species residue data for most of the rodenticide active ingredients evaluated (Tables 11 and 15), the USEPA did not even attempt to use this information to assess either secondary exposures or secondary risks to birds or nontarget mammals. In fact, the USEPA made no attempt to quantitatively estimate secondary exposure at all, except to use blood and liver retention times as potential surrogates. The CDFA encourages the USEPA to change its approach and use the available residue data to directly estimate secondary exposure rather than rely on surrogate data that is potentially unreliable (see additional discussion of surrogate data below).

3. The USEPA blamed the unavailability of typical use information (e.g., amount of rodenticide active ingredient or formulated product applied per area) for not estimating nontarget organism exposure (PCEA Executive Summary and Page 1). Much of this information can easily be taken from product labels and other sources available to the Agency, but would require a product-by-product analysis, rather than the "generic" approach chosen by the USEPA in the PCEA.

4. The Agency must move beyond the generic approach that it has used and identify specific species of concern in the risk assessment. Clearly exposures and risks are not the same for all birds and mammals because of many factors (e.g., diet and food preferences, proximity of habitat to use areas, home range, etc.); however, the only factor that the Agency has considered at all in the PCEA is body size and its relationship to food intake. The Agency should identify receptors of concern to evaluate in the risk assessment. These receptors will differ for different types of rodenticides (e.g., grain baits versus wax pellets) and use

patterns (e.g., in and around homes versus orchards versus rangeland). Once the receptors have been identified, the Agency can develop exposure profiles on a species-by-species basis and then integrate this information with toxicity data to estimate the true likelihood of risks.

Issues With the Data Used in the Assessment

1. A significant flaw in the USEPA's methodology is that many of the measures of effect values it used were based on data that are not directly comparable and therefore should not be used to develop comparative measures of effect or ranking values. For example, the primary measure of effect for evaluating secondary risk to both birds and nontarget mammals was the mean percent mortality in all laboratory secondary hazard studies. For some active ingredients there were many secondary hazard studies, for others there were few or none. Even when many studies were available, they were not based on a common study protocol or the USEPA Guideline. They used many different species (both as the target and nontarget), exposure levels, feeding regimens, and even different bait strengths in some cases. Most of these studies were designed to evaluate the potential hazards of field uses, not "in and around home" uses of rodenticides. The results of all secondary hazard studies designed to evaluate the potential hazards for field products and uses are not directly comparable to those for other products and use patterns and should not be lumped together and evaluated as a whole group as the USEPA did in the PCEA. This effectively amounts to using hazard data for a few specific products and use patterns to evaluate all other products and use patterns for the active ingredient. This is a biased and unscientific use of data.

2. The USEPA used non-comparable data for certain blood and liver retention times in its analysis. Some values used were from studies with humans, while others were from studies with rats, pigs, and even cattle. Metabolism and thus retention times can and do vary significant between species, therefore it is inappropriate to base measures of effect on these factors unless data are from the same species and were generated under similar testing conditions and protocols. An even more significant problem is that half-lives and retention times cannot be used interchangeably, as was done throughout the USEPA's analysis. The half-life for a compound is independent of dose (unless elimination kinetics are saturated), but the retention time is not. Therefore, the study design and dosing regimen will affect the retention time more than the half-life. Again, because conditions were not standardized and comparable in the studies from which retention time data were derived, this causes a bias in the dataset. Furthermore, it must be kept in mind that the retention time will always be longer than half-life for a given compound, therefore, use of retention times will bias the dataset for certain compounds unless this data is used for all compounds in the analysis.

3. Where no data were available, the specific measure of effect was not included in the analysis for that particular active ingredient. This caused an overweighing of values for those measures of effect where data were available and biases the outcome of the assessment depending on whether the available data are favorable or unfavorable.

4. The validity and reliability of the cited data were not assessed and no indication was given on whether data were generated under Good Laboratory Practices regulations.

5. It is apparent that several of the secondary hazard studies were not reviewed or evaluated by the USEPA and data from them were directly cited from secondary sources (i.e., Joermann, 1998). Despite this and the fact that some of these studies evaluated

products and use patterns that are not registered in the United States (e.g., bait strengths of 0.075 percent a.i.), results of these studies were used to determine measure of effect values in the PCEA.

Subchronic Mammalian Toxicity Data Not Utilized

1. Despite the availability of a large set of subchronic mammalian toxicity studies, including studies on most, if not all, of the nine active ingredients, the USEPA has not utilized (or even discussed) this data in the PCEA. Subchronic studies on rats, mice and rabbits were discussed at length in the Rodenticide Cluster RED (USEPA, 1998), but have been totally ignored in the PCEA. This is troubling since data from these studies (e.g., NOELs) may be easily used to directly characterize the risks (or compare the hazards) of different rodenticides to nontarget mammals, whether using the "generic" approach used by the Agency in the PCEA or a risk quotient approach that takes into account estimates of exposure. The USEPA typically uses rat and mouse toxicity data as a surrogate for wild mammals in its ecological risk assessments, but did not do so in the PCEA for some reason. The CDFA encourages the USEPA to use the available mammalian toxicity data that it has required registrants to generate in order to improve the risk assessment. Use of this data for risk assessment would be more appropriate than using the collective mortality data from mammalian secondary hazard studies, particularly when the secondary hazard data have limited applicability in terms of products and use patterns.

Ecological Adversity Not Considered by the USEPA

1. Although the USEPA has characterized the risks for different rodenticide active ingredients to birds and nontarget mammals as "high", "moderate" or "low" (Table 47), it has not attempted to describe any of these "risks" in terms of ecological adversity to the populations or ecological entities at potential risk. This should be a part of the risk description as discussed in the USEPA's Guidelines for Ecological Risk Assessment (USEPA, 1998, Section 5.5.5). The degree of ecological adversity is important because it must be taken into consideration when weighing risks and benefits and determining whether risk mitigation measures are necessary. According to the USEPA's Guidelines, the evaluation of ecological adversity should take into account 1) the nature of effects and intensity of effects, 2) the spatial and temporal scale of effects, and 3) the potential for recovery. None of this has been done in the preliminary ecological assessment as it now stands.

Comments on Uncertainty in the Assessment

1. The USEPA discusses a number of factors that contribute to uncertainty in the risk assessment including missing data, data of variable quality, and specific use information. The USEPA also acknowledges that "additional data to fill-in where data are missing or standardize data where the quality is variable, as well as specific use and exposure information will likely provide the greatest reduction in uncertainty for these analyses." However, the USEPA does not explain or discuss how it intends to reduce this uncertainty in the assessment except to say that it will require avian reproductions studies for all of the rodenticides with outdoor use patterns. The CDFA agrees that there is considerable uncertainty in the USEPA's analysis because of missing data or use of biased data. This uncertainty should be addressed unless it is clear that new data will have no influence on the final outcome of the assessment. Much of this uncertainty could be directly eliminated through a change in assessment methodology so that secondary exposure is directly

assessed (e.g., through use of residue data) rather than by using surrogate information such as liver and blood retention times or half lives.

Comments in Regard to the CDFA's FIFRA Section 24c Rodenticides

Use and Risks of the CDFA's 0.01% a.i. and 0.005% a.i. Rodent Baits

1. The USEPA is inconsistent in its "risk" evaluations for chlorophacinone and diphacinone. In some cases the USEPA differentiates between bait strengths of 0.005% (50 parts per million) (ppm) and 0.01% (100 ppm) in their analyses, but in other cases they do not (i.e., secondary risks to birds and mammals), even when data are available to do so (See Tables 12 and 13, 20 and 21). In the subjective risk presumption ratings (i.e., high, moderate, or low) in (Table 47), the USEPA does not specify which bait strengths of chlorophacinone and diphacinone are being rated and does not differentiate between the two. However, in the PCEA text (Page 95) the USEPA states "Distinctions cannot be made between the 50 ppm and 100 ppm chlorophacinone and diphacinone baits in the incident data, but the 100 ppm baits are likely to present greater risk than the 50 ppm." This conclusion is contrary to results of the Comparative Analysis Model in (Table 46), where summary values for the two bait strengths are almost identical and do not indicate a difference in risk. The CDFA believes that it is possible to differentiate potential risks between 50 and 100-ppm baits, but that the USEPA was unable to do so because of the flawed methodology used in the PCEA to evaluate potential secondary risks for birds and nontarget mammals. For example, there was no attempt to use residue data in the PCEA to estimate potential exposure levels for birds and nontarget mammals, rather, retention times and/or half-lives in the blood and liver were used as a surrogate for exposure and were assumed to be the same for both bait strengths. The inherent toxicity (e.g., LD50) of the active ingredient itself does not change with bait strength, only the potential exposure level changes, therefore, it is necessary to evaluate exposure if you are to differentiate the risks of products with the same active ingredient but different bait strengths. Because the CDFA's two bait strengths are not used interchangeably (e.g., 50 ppm baits are used in bait stations, 100 ppm baits are used for broadcast), it is totally inappropriate to assume that the secondary exposure from 100-ppm baits is twice (or even greater than) the secondary exposure from 50-ppm baits. This may or not be the case depending on many factors, of which bait strength is only one. As discussed above, the exposure analyses must take into account product-specific factors such as the application method and rate, use site, target species, etc. One way to do this is to use target species residue data that has been generated for the specific rodenticide and use pattern being evaluated.

Product-Specific Factors Affecting Risks to Birds and Nontarget Mammals

1. The USEPA's evaluation of primary risks to birds does not take into account the fact that dyes that are added to the CDFA's rodent grain baits in order to deter consumption by birds. A black dye is added to the zinc phosphide baits and a blue dye is added to the baits containing chlorophacinone and diphacinone. There is a large body of research that shows that these dyes will deter consumption of grain by birds (Kalmbach, 1943; Kalmbach and Welch, 1946; Pank, 1976; Marsh, 1985; Greig-Smith and Rownet, 1987; Robel et al., 1997; Moran, 1999); however, this information was totally ignored by the USEPA. In fact, the USEPA states that "there is no doubt that many birds and nontarget mammals are attracted to and will consume grain-based foods" (PCEA, Page 8) and assumes in the PCEA that the bait will make up 100 percent of a bird or mammal's diet. This type of simplistic analysis is

unfair to products such as the CDFA's that contain a dye in order to minimize risks to birds and other wildlife.

2. The USEPA does not differentiate between different types of grains in its analysis. However, in order to discourage bait consumption by birds, the CDFA specifies use of only lightly rolled or crimped oat groats[1] as the base material in its rodent baits. Rolling or crimping creates flattened kernels, which alters their natural appearance, and when dyed are thought to appear larger and less attractive to birds than nonrolled kernels of the same grain (Marsh, 1985). Rolled grain also deteriorates more rapidly under moist or wet conditions, which reduces the time that the grain is available for consumption in the field time. Use of "lightly" rolled oats for the bait minimizes the presence of fine, broken grain particles which are too small for rodents to manipulate, but may be acceptable to small seed-eating birds. In addition, use of oats, rather than wheat or milo, reduces the potential for nontarget hazard because this grain is less apt to be consumed by certain large seed-eating birds (Marsh, 1985).

3. The USEPA's analyses of primary risks to both birds and nontarget mammals assume that all rodent baits weigh 0.2 g per pellet or kernel. There are typically 16,000 to 20,000 grain kernels per pound in the CDFA's rodent baits, with a mean of 18,000 kernels per pound. This means that the average kernel weights only 0.025 grams, or almost 10-fold less than assumed by the USEPA in the PCEA. This greatly reduces the potential primary risks of the CDFA's baits to birds and nontarget mammals compared to other rodenticide products. Based on acute oral toxicity data for the northern bobwhite (LD50 = 258 mg chlorophacinone/kg), a small 25-g granivorous bird would need to consume approximately 64.5 grams of 0.01 percent chlorophacinone rodent bait (and even more of the 0.01 percent diphacinone bait) in order to receive a lethal dose. Consumption of this amount of bait in a short period is very unlikely because it represents more than twice the body weight of the bird. Because of the small grain size, this bird would need to consume approximately 5,160 kernels of bait in order to receive a lethal dose, a very unlikely scenario considering the low bait density (approximately 3 to 5 kernels/ft^2 when mechanically broadcast) and the effectiveness of the target species in finding and removing bait.

4. The USEPA's analysis does not account for the fact that all of the CDFA's rodent baits are already classified as "restricted use", or will be after the reregistration labels are approved by the USEPA. The USEPA acknowledges that this classification provides increased protection of birds and nontarget mammals because baits may only be applied by a Certified Applicator or someone under his or her direct supervision (PCEA, Page 7), but fails to take this fact into consideration when either quantitatively or qualitatively describing risks in the PCEA.

Specific Errors and Omissions

1. The blood retention time for diphacinone 50-ppm bait in (Table 41) appears to be incorrect based on data in (Table 1 and Table 4 of Attachment C). This number should be 17.50 as is the case for the diphacinone 100 ppm bait.

[1] "Oat groats" refers to oats from which the hulls have been removed, but not altered in any other way.

2. In (Tables 11 and 15) the main document do not contain liver or blood retention time data as is stated several times in the document (e.g., footnote b in Tables 40 and 41 and in Attachment C). The retention time actually data come from (Tables 33 and 37).

Recommendations

The CDFA recommends the following process to the USEPA for following up on its preliminary ecological assessment:

1. Address or eliminate the uncertainties in the assessment to the extent possible by changing the analysis methodologies and requiring new data where absolutely necessary.

2. Once the uncertainties have been addressed, conduct a refined ecological assessment that evaluates potential exposure and compares only products with a similar use pattern (e.g., compares only "in and around home" rodenticides to each other). The refined assessment should include the following:

    - Use of residue data to evaluate secondary exposure to specific receptors of concern

    - Use of mammalian subchronic toxicity data to evaluate secondary exposure risks to nontarget mammals

    - Use of avian subacute toxicity or avian reproduction data to evaluate secondary exposure risks to birds

3. Once complete, the results of the refined assessment should be used to conduct more in-depth analyses of individual rodenticide products and to determine whether risk mitigation measures are justified after consideration of product benefits.

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